K023264

SUMMARY OF SAFETY AND EFFECTIVENESS
ALARIS Medical Systems®
MEDLEY™ Syringe Pump Module

SUBMITTER INFORMATION

A.	Company Name:	ALARIS Medical Systems, Inc.
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7563 (858) 458-6114
D.	Contact Person:	Renée L. Fluet Principal Regulatory Affairs Specialist ALARIS Medical Systems, Inc.
E.	Date Summary Prepared:	September 27, 2002

DEVICE IDENTIFICATION

A.	Generic Device Name:	Syringe Infusion Pump
B.	Trade/Proprietary Name:	MEDLEY™ Syringe Pump Module
C.	Classification:	Class II
D.	Product Code:	FRN, Infusion Pump

DEVICE DESCRIPTION

The MEDLEY Syringe Pump Module functions as part of the MEDLEY™ Medication Safety System. In combination with the MEDLEY™ Programming Module (PM), the Syringe Module will deliver fluids in a manner similar to current syringe pumps on the market. Up to four Syringe Modules may be connected to each PM.

SUMMARY OF SAFETY AND EFFECTIVENESS
Page 2

DEVICE DESCRIPTION (Continued)

The MEDLEY™ Syringe Pump uses standard, single-use, administration sets (with and without pressure disc) and syringes with luer-lock connectors, of type designed for use on syringe pumps. The MEDLEY™ Syringe Pump may be used with administration sets that contain a pressure disc. If the pressure disc is used, the following features are available:

- Back-off
- Fast Start
- Customizable Pressure Alarm Settings
- Pressure Tracking Display
- Auto Pressure

SUBSTANTIAL EQUIVALENCE

The ALARIS Medical Systems® MEDLEY™ Syringe Pump is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Model P7000 Variable Syringe Pump	ALARIS Medical Systems, Inc.	K974332	12/29/98
Medex 3000 Series Syringe Infusion Pump, Model 3010a	Medex, Inc.	K982640	4/6/99

INTENDED USE

The MEDLEY™ Syringe Pump is intended for use in today's growing professional healthcare environment for facilities that utilize syringe pumps for the delivery of fluids, medications, blood and blood products.

The MEDLEY™ Syringe Pump is indicated for use on adults, pediatrics and neonates for continuous or intermittent delivery through clinically acceptable routes of administration

SUMMARY OF SAFETY AND EFFECTIVENESS
Page 3

INTENDED USE (Continued)

such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the MEDLEY™ Syringe Pump and the predicate devices has been performed. The results of this comparison demonstrate that the MEDLEY™ Syringe Pump is equivalent to the marketed predicate devices in technological characteristics.

PERFORMANCE DATA – The performance data indicate that the MEDLEY™ System Syringe Pump meets specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2002

Ms. Renée L. Fluet
Principal Regulatory Affairs Specialist
ALARIS Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121-2733

Re: K023264
Trade/Device Name: MEDLEY™ Syringe Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: September 27, 2002
Received: September 30, 2002

Dear Ms. Fluet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K023264 (To Be Assigned By FDA)

Device Trade Name: **MEDLEY™ Syringe Pump**

Indications For Use: The MEDLEY™ Syringe Pump is intended for use in today's growing professional healthcare environment for facilities that utilize syringe pumps for the delivery of fluids, medications, blood and blood products.

The MEDLEY™ Syringe Pump is indicated for use on adults, pediatrics and neonates for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irrigation of fluid spaces.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023264